REQUEST FOR FILING NATIONAL PATENT APPLICATION

Under 35 USC 111(a) and Rule 53(b)

(Not for Provisional or PCT cases)

PATENT APPLICATION

Assistant Commissioner of Patents
Washington, D.C. 200231

WITH SIGNED DECLARATION

NONPROVISIONAL

Herewith is the PATENT APPLICATION of
Inventor(s): JOHNSON, Lanny L.

(Our Deposit Account No. 03-3975)
Our Order No. 40858 (C#) 225528 (M#)

Title FEMORAL PROSTHESIS

Atty. Dkt.: PMS 225528 (M#) (Client Ref)

including:

Date: June 12, 1998

1. Specification: 7 pages (only spec. and claims) 2. ☐ Specification in non-English language
3. Declaration ☒ Original ☐ Facsimile/Copy ☒ Abstract 1 page(s); 12 numbered claims
3 (a). ☒ Drawings: 5 sheet(s) ☒ informal; ☒ formal of size: ☒ A4 ☐ 11" ☐ 13"
4. **AMEND the specification** please by inserting before the first line: — This is a ☐ Continuation-in-Part ☐ Divisional ☐ Continuation ☐ Substitute Application (MPEP 201.09) of:
4(a) ☐ National Appln. No. / filed . (M#)
4(b) ☐ International Appln. No. filed which designated the U.S.
5. ☐ See top first page re continuing application ("X" box only if information is there)
6. ☐ Attached is an assignment and cover sheet. Please return the recorded assignment to the undersigned.
7. ☐ Prior application is assigned to

by Assignment recorded Reel Frame
8. **FOREIGN** priority is claimed under 35 USC 119(a)-(d)/365(b) based on filing in
9.

Application No.	Filing Date	Application No.	Filing Date
(1)		(2)	
(3)		(4)	
(5)		(6)	
(7)		(8)	
(9)		(10)	

10. (No.) Certified copy (copies): ☐ attached; ☐ previously filed (date)
in U.S. Application No. / filed on
11. ☒ Attached: 1 (No.) Verified Statement(s) establishing "small entity" status under Rules 9 & 27.
12. **DOMESTIC/INTERNATIONAL** priority is claimed under 35 USC 119(e)/120/365(c) based on the following provisional, nonprovisional and/or PCT international application(s):

Application No.	Filing Date	Application No.	Filing Date
(1)		(2)	
(3)		(4)	
(5)		(6)	
(7)		(8)	
(9)		(10)	

13. ☐ Attached:

14. ☐ This application is being filed under Rule 53(b)(2) since an inventor is named in the enclosed Declaration who was not named in the prior application.

15. ☐ Preliminary Amendment:

THE FOLLOWING FILING FEE IS BASED ON CLAIMS AS FILED LESS ANY ABOVE CANCELLED

				Large/Small Entity		Fee Code
16. Basic Filing Fee				$790/$395	$395	101/201
17. Total Effective Claims	12	minus 20 =	*0	x $22/$11 =	+ 0	103/203
18. Independent Claims	1	minus 3 =	*0	x $82/$41 =	+ 0	102/202
*If answer is zero or less, enter "0"						
19. If any proper multiple dependent claim (ignore improper) is present , add (Leave this line blank if this is a reissue application)				+ $270/$135	+ 0	104/204
20. TOTAL FILING FEE ENCLOSED =					$395	
21. If "non-English" box 2 is X'd, add Rule 17(k) processing fee				+ $130/$130	+ 0	139
22. If "assignment" box 6 is X'd, add recording fee				+ $40/$40	+ 0	581
23. ☐ Attached is a Petition/Fee under Rule No.				+ $130/$130	+ 0	122
24. TOTAL FEE ENCLOSED =					$395	

CHARGE STATEMENT: The Commissioner is hereby authorized to charge any fee specifically authorized hereafter, or any missing or insufficient fee(s) filed, or asserted to be filed, or which should have been filed herewith or concerning any paper filed hereafter, and which may be required under Rules 16-18 (missing or insufficient fee only) now or hereafter relative to this application and the resulting Official document under Rule 20, or credit any overpayment, to our Account/Order Nos. shown in the heading hereof for which purpose a duplicate copy of this sheet is attached.

This CHARGE STATEMENT does not authorize charge of the issue fee until/unless an issue fee transmittal form is filed.

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NOTE: **File in duplicate with 2 post card receipts (PAT-103) & attachments**

APPLICATION UNDER UNITED STATES PATENT LAWS

Invention: FEMORAL PROSTHESIS

Inventor (s): Lanny L. JOHNSON

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This is a:

- ☐ Provisional Application
- ☒ Regular Utility Application
- ☐ Continuing Application
- ☐ PCT National Phase Application
- ☐ Design Application
- ☐ Reissue Application
- ☐ Plant Application
- ☐ Substitute Specification
  Sub. Spec Filed _____
  in App. No. __/_____

SPECIFICATION

FEMORAL PROSTHESIS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a femoral prosthesis, and more particularly, to a prosthesis design which provides an improved fit within the intramedullary canal of the femur.

2. Prior Art

It is well known that the shape of the femoral intramedullary canal is variable. Thus, when a prosthesis is implanted within the canal, it must be properly fitted. If the prosthesis bears on a particular area of cortical bone surrounding the canal, pain may be experienced by the recipient of the prosthesis. Additionally, the prosthesis may loosen as a result of rotation within canal or because of downward pressure resulting from the weight of the user.

The geometry of the femoral intramedullary canal is that it has an oval shape in its upper portion adjacent the location where the femoral head and neck have been removed. The major axis of the oval extends in the medial to lateral direction. However, approximately 4 to 6 inches below its upper end, the canal narrows, and it transitions to a configuration in which it is oval shaped, the oval's major axis extending in the anterior/posterior direction.

Conventional femoral prostheses neglect the geometrical characteristics of the intramedullary canal just described. More particularly, while they are configured to accommodate the canal's proximal geometry, they typically have distal portions which are circular in cross-section. Thus, proper fitting of such prostheses is achieved only at the proximal end of the

canal. This results in less than complete stable fixation leading to the problems previously described.

SUMMARY OF THE INVENTION

The present invention overcomes the shortcomings of prior art femoral prostheses by providing a femoral stem which has a substantially oval configuration over its entire length, the stem being provided with a twisted waist intermediate its ends whereby the major axis of the oval transitions by approximately 90°. This permits an implanted prosthesis to approximate the geometry of the intramedullary canal within which it is received.

DESCRIPTION OF THE DRAWINGS

The invention will be described in greater detail with respect to the accompanying drawings wherein:

FIG. 1 is a side elevational view the femoral stem of a conventional prosthesis;

FIG. 2 is an end elevational view of a portion of the femoral stem shown in FIG. 1;

FIGS. 3 and 4 illustrate the femoral stem of FIG. 1 as it is received within a femoral intramedullary canal;

FIG. 5 is a side elevational view of the femoral stem of a prosthesis according to the present invention;

FIG. 6 is an end elevational view of a portion of the femoral stem shown in FIG. 6;

FIGS. 7 and 8 illustrate the femoral stem of FIG. 5 as it is received within a femoral intramedullary canal; and

FIGS. 9 and 10 diagrammatically illustrate the displacement of cancellous bone as the femoral stem is inserted within an intramedullary canal.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT OF THE INVENTION

Referring to FIGs. 1 and 2, a conventional femoral stem 10 is illustrated. The stem at its proximal end is provided with a neck 12 for receiving a head (not shown). As can be appreciated from FIGs. 1 and 2, the proximal portion of the stem below neck 12 has an oval cross-section. Substantially midway along its length the cross-section of the stem transitions to one which is substantially circular, and the cross-section so remains to the distal end of the stem.

FIGs. 3 and 4 illustrate the positioning of the stem 10 within the intramedullary canal 14 of a femur 16. FIG 3 presents a medial/lateral view of the canal, while FIG. 4 shows the canal in a anterior/posterior sense.

As can be appreciated from FIGs. 3 and 4, the stem 10 provides a fit with canal 14 which is stable in the medial to lateral direction at both the proximal and distal ends of the stem. However, because the distal end of stem 10 is substantially circular in cross-section, a very loose fit exists between the stem's distal end and the wall of the canal in the anterior/posterior direction. This significant spacing provides an opportunity for the prosthesis to loosen.

FIGs. 5 and 6 illustrate a femoral stem 18 according to the invention wherein below a neck 20, the stem is tapered towards its distal end. The cross-section of the stem 18 is oval shaped. At its proximal portion, the major axis of the cross-section extends in the medial/lateral direction (FIG. 5). However, substantially midway along the length of the stem, a twisted waist 22 is provided which transitions of stem's oval-shaped cross-section by approximately 90° to one in which the major axis of the oval at the stem's distal end extends in the anterior/posterior direction (FIG. 6).

As can be appreciated from FIGs. 7 and 8, with stem 18 inserted within the intramedullary canal, a close fits is achieved between the stem and the canal's wall along the entire length of the stem. As a result, the likelihood that the stem will loosen within the canal is greatly diminished.

To ascertain the dimensions of a recipient's intramedullary canal, conventional pre-operative measurement in the form of x-rays may be employed. Additionally, the internal dimensions can be measured utilizing the instrument disclosed in applicant's co-pending U.S. Application No. 08/840,548, filed on February 26, 1998, which is a continuation of U.S. Application No. 08/389,399, filed on February 16, 1995. That instrument comprises a rod having fins fixed at its distal end. The rod is inserted within the intramedullary canal until the fins contact the cortical bone which defines the wall of the canal. As a result, a central bone is formed in the canal, and the fins permit a measurement of the size of the canal at the depth at which the fins engage the wall. By using a series of such instruments having different sizes, the dimensions of the canal can be plotted.

After determining the canal's configuration and size, a series of smooth broaches having the same geometry as the femoral stem, but of successively larger sizes, are inserted into the intramedullary canal. In order to pass through the portion of the canal at which it transitions from being oval-shaped in the medial/lateral direction to the anterior/posterior direction, the broaches require their being twisted when their distal ends reach the transition area of the canal.

As broaches of increasingly greater size are inserted within the canal, the cancellous bone within the distal portion of the canal is compacted to increase its density. This form of compaction by the use of a series of broaches is disclosed in U.S. Application No. 08/734,383, filed on October 17, 1996. The compacted bone provides a dense bed against which the distal end of the femoral stem rests when the stem subsequently is inserted into the canal in the same way described with respect to the broaches. The compacted bed provides further resistance against loosening of the prosthesis.

During preparation of the canal and insertion of the femoral stem, the twisting of the broaches and the stem causes displacement of cancellous bone in the proximal portion of the canal. More particularly, and as illustrated in FIGs. 9 and 10, the fact that upper end of the canal is open results in some of

the cancellous bone 24 being compacted within the canal's proximal end (FIG. 10). However, a void 26 also is created (FIGs. 9 and 10), and this requires that cancellous bone harvested when the recipient's natural femoral head was removed be deposited in the void and compacted after the femoral stem is in place. This results in a tight bone mass which firmly supports the stem's proximal portion.

Although not specifically disclosed in applicant's prior U.S. Application No. 08/840,548, the bore-forming and measuring device for the intramedullary canal can include a tube so as to permit suction of the bone marrow to remove fat and decompress pressure in the canal as the bore is formed.

The prosthesis which has been described permits a very close fit along its entire length with the wall of the intramedullary canal. While the invention contemplates the use of a metal femoral stem because the space between the stem and the canal's wall is filled with compacted bone, it becomes possible to use a stem made from biodegradable material to achieve a true anatomic result.

Although the femoral stem illustrated contains a neck to which the head portion of the prosthesis can be attached, it will be understood that the stem may have a one piece neck and head.

It further will be understood that the prosthesis described, and the broaches used to prepare the site for insertion of the femoral stem, dictate that they are usable on only one side of the body. Thus, separate sets for left and right side applications are required.

What Is Claimed Is:

1. A femoral prosthesis, comprising:

a femoral stem tapered from a proximal end to a distal end thereof, said stem having a substantially oval-shaped cross-section along its length and including a twisted waist portion intermediate its ends whereby major axes of the oval cross-section located on opposite sides of the waist portion extend in different directions.

2. A femoral prosthesis according to Claim 1, wherein said stem is formed of metal.

3. A femoral prosthesis according to Claim 1, wherein said stem is formed of a biodegradable material.

4. A femoral prosthesis according to Claim 1, wherein the directions of the major axes are disposed at an angle of substantially 90° with respect to one another.

5. A femoral prosthesis according to Claim 4, wherein said stem is formed of metal.

6. A femoral prosthesis according to Claim 4, wherein said stem is formed of a biodegradable material.

7. A femoral prosthesis according to Claim 1, wherein the twisted waist portion is located substantially midway between the ends of the stem.

8. A femoral prosthesis according to Claim 7, wherein said stem is formed of metal.

9. A femoral prosthesis according to Claim 7, wherein said stem is formed of a biodegradable material.

10. A femoral prosthesis according to Claim 1, wherein the twisted waist portion is located substantially midway between the ends of the stem and the directions of the major axes on opposite sides of the waist portion are disposed at an angle of substantially 90° with respect to one another.

11. A femoral prosthesis according to Claim 10, wherein said stem is formed of metal.

12. A femoral prosthesis according to Claim 10, wherein said stem is formed of a biodegradable material.

ABSTRACT

A femoral prosthesis includes a stem tapered from its proximal end to its distal end, the stem having a substantially oval-shaped cross-section along its length. The stem has a twisted waist portion intermediate its ends whereby the major axes of the cross-section on opposite sides of the waist portion are disposed at an angle of approximately 90° with respect to one another so as to conform with the geometry of an intramedullary canal within which the stem is to be received.

FIG. 1

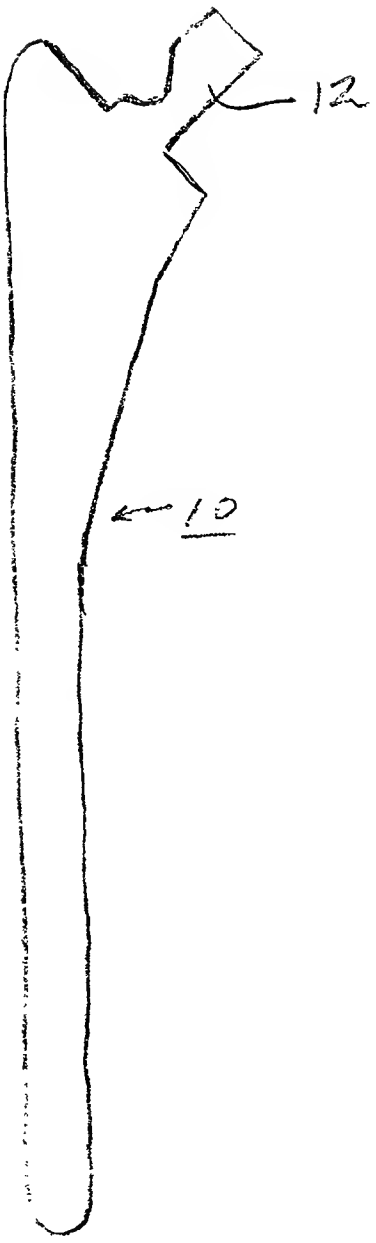


FIG. 2

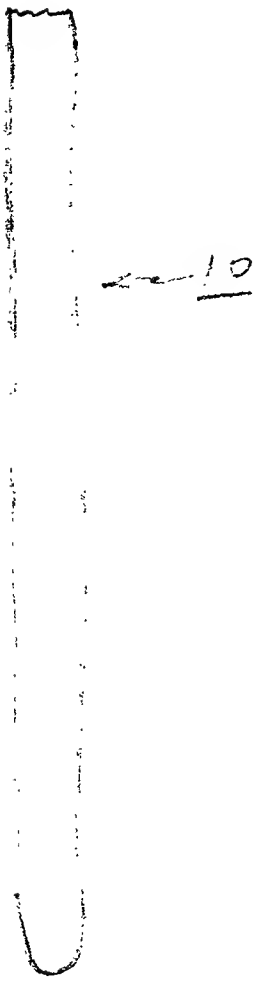


FIG. 3

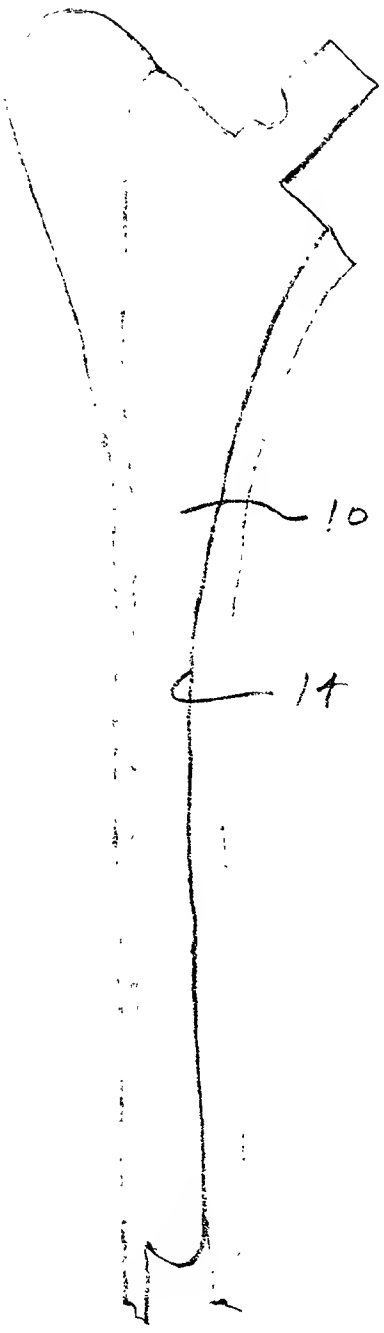


FIG. 4

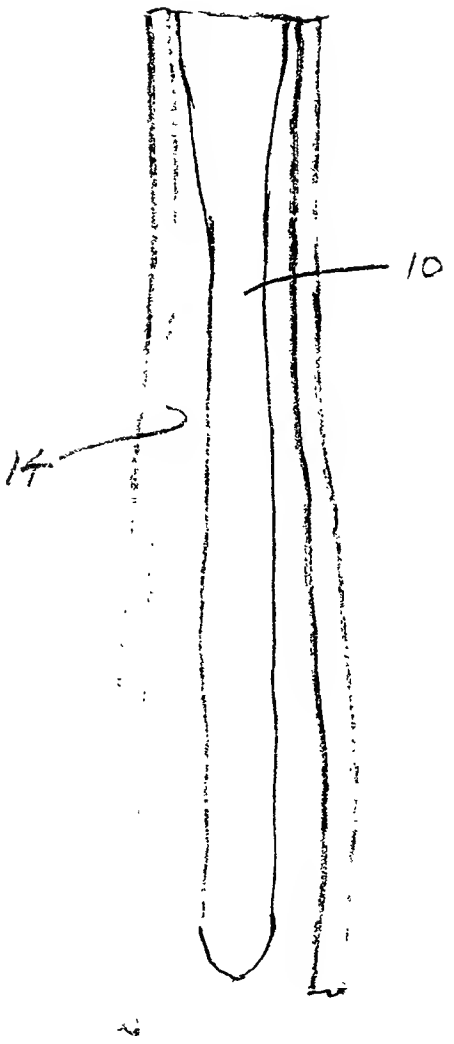


FIG. 5

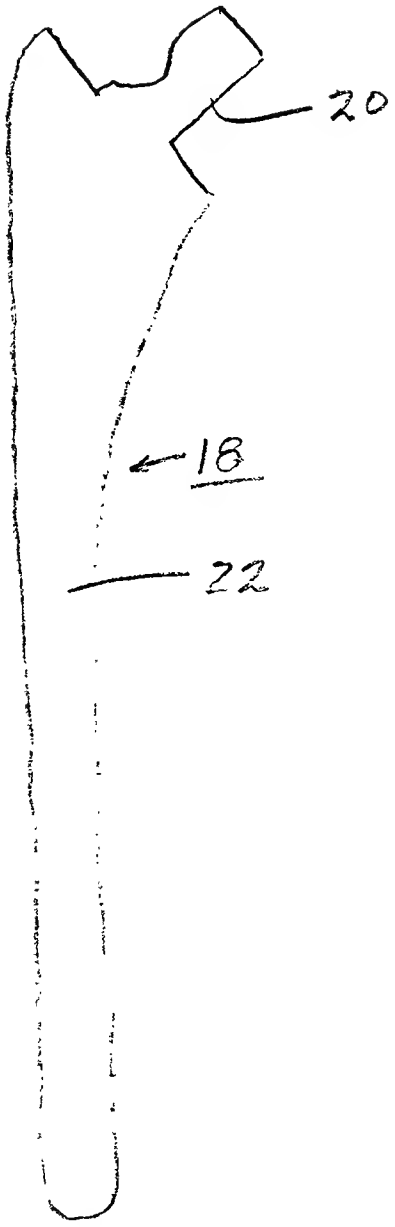


FIG. 6

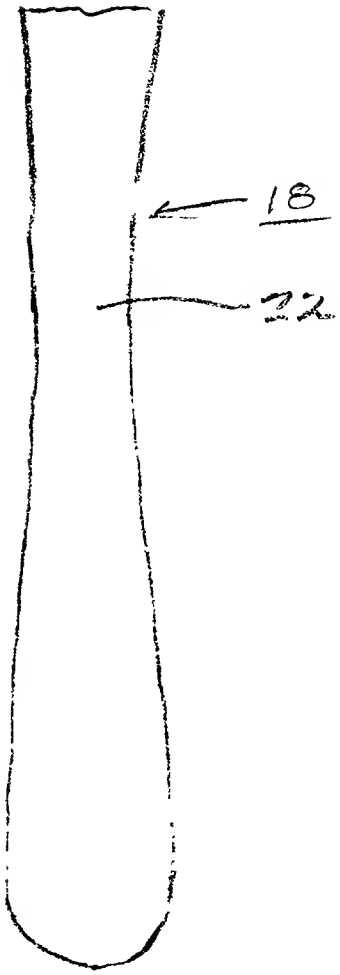


FIG. 7

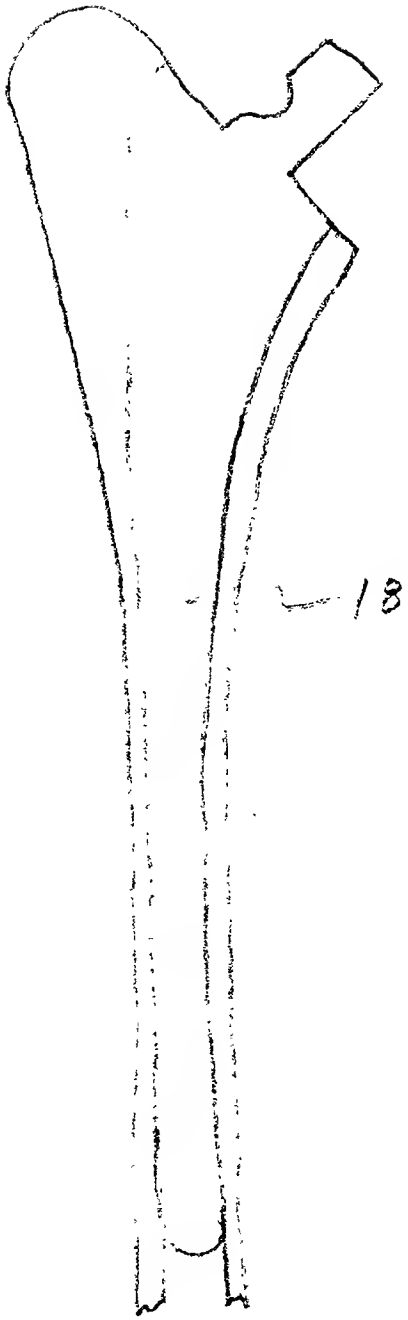


FIG. 8

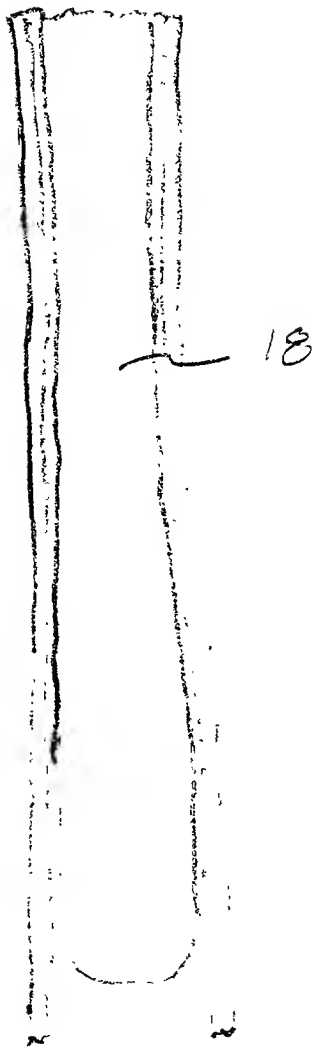


FIG. 9

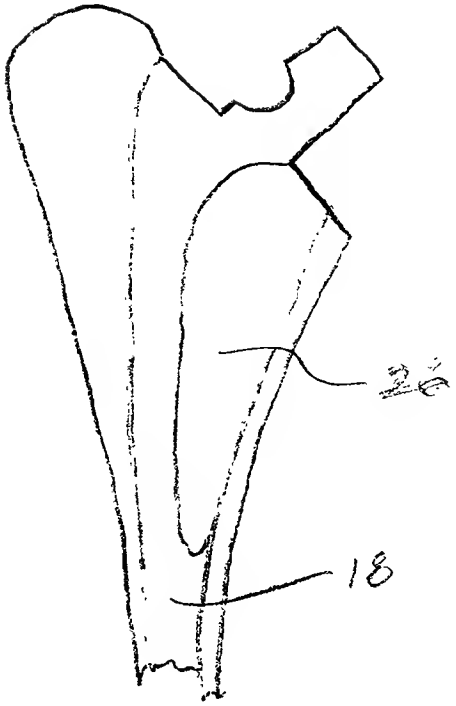
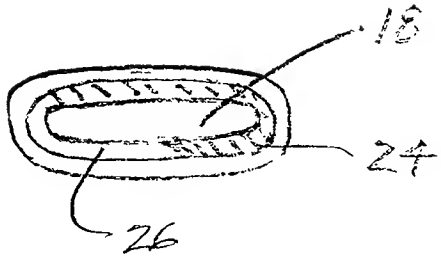


FIG. 10



Inventor(s): JOHNSON
Appln. / or Patent No.:
Atty. Dkt.
PMS 225528/
M# / Client Ref.

Filed: or Issued:

For: FEMORAL PROSTHESIS

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27 (b)) - **INDEPENDENT INVENTOR**

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled as above and described in

X ☒ the specification filed herewith
one → ☐ Application No. __/_____, filed
box → ☐ Patent No. _____, issued

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, convey or license any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).:

Each (small entity) person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention

X → ☒ there is no such person, concern, or organization.
one → ☐ such persons, concerns or organizations are listed in (A) and (B) below:

(A) FULL NAME of assignee/licensee/grantee/conveyee*
ADDRESS
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

(B) FULL NAME of assignee/licensee/grantee/conveyee*
ADDRESS
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

*NOTE: Separate verified statement is required from each person, concern or organization named in (A) and (B) above having rights to the invention, averring to his/her/its status as a small entity. (37 CFR 1.27)

I acknowledge the duty to file, in this case, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

1.	2.	3.
Lanny L. JOHNSON		
NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
X Lanny L. Johnson		
Signature of Inventor	Signature of Inventor	Signature of Inventor
X 5/26/98		
Date	Date	Date

PAT-138 11/97

FOR UTILITY/DESIGN CIP/PCT NATIONAL/PLANT ORIGINAL/SUBSTITUTE/SUPPLEMENTAL DECLARATIONS

RULE 63 (37 C.F.R. 1.63) DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PM & S FORM

As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name, and I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the **INVENTION ENTITLED FEMORAL PROSTHESIS**

the specification of which (CHECK applicable BOX(ES))

X → ☒ is attached hereto.

BOX(ES) → ☐ was filed on _____ as U.S. Application No. _____/_____

→ → ☐ was filed as PCT International Application No. PCT/_____/_____ on _____

and (if applicable to U.S. or PCT application) was amended on _____

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose all information known to me to be material to patentability as defined in 37 C.F.R. 1.56. I hereby claim foreign priority benefits under 35 U.S.C. 119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate filed by me or my assignee disclosing the subject matter claimed in this application and having a filing date (1) before that of the application on which priority is claimed, or (2) if no priority claimed, before the filing date of this application:

PRIOR FOREIGN APPLICATION(S) Number	Country	Day/MONTH/Year Filed	Date first Laid-open or Published	Date Patented or Granted	Priority Claimed Yes	No

I hereby claim domestic priority benefit under 35 U S.C. 119/120/365 of the indicated United States applications listed below and PCT international applications listed above or below and, if this is a continuation-in-part (CIP) application, insofar as the subject matter disclosed and claimed in this application is in addition to that disclosed in such prior applications, I acknowledge the duty to disclose all information known to me to be material to patentability as defined in 37 C.F.R. 1.56 which became available between the filing date of each such prior application and the national or PCT international filing date of this application.

PRIOR U.S. PROVISIONAL, NONPROVISIONAL AND/OR PCT APPLICATION(S) Application No. (series code/serial no.)	Day/MONTH/Year Filed	Status pending, abandoned, patented	Priority Claimed Yes	No

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

And I hereby appoint Pillsbury Madison & Sutro LLP, Intellectual Property Group, 1100 New York Avenue, N.W., Ninth Floor, East Tower, Washington, D.C. 20005-3918, telephone number (202) 861-3000 (to whom all communications are to be directed), and the below-named persons (of the same address) individually and collectively my attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith and with the resulting patent, and I hereby authorize them to delete names/numbers below of persons no longer with their firm and to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/ organization who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct the above Firm and/or a below attorney in writing to the contrary.

Paul N. Kokulis	16773	Edward M. Prince	22429	Michelle N. Lester	32331	Ruth N. Morduch	31044
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G. Lloyd Knight	17698	Donald J. Bird	25323	Lynn E. Eccleston	35861	Roger R. Wise	31204
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Edgar H. Martin	20534	Dale S. Lazar	28872	David A. Jakopin	32995	Anita M. Kirkpatrick	32617
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(include Zip Code)	48864		

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	First	Middle Initial	Family Name
Residence			
	City	State/Foreign Country	Country of Citizenship
Post Office Address			
(include Zip Code)			

(FOR ADDITIONAL INVENTORS, check box ☐ to attach PAT 116-2 same information for each re signature, name, date, citizenship, residence and address.)